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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/527,772

04/18/2005

Kenji Tanaka

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LEYDIG VOIT & MAYER, LTD
TWO PRUDENTIAL PLAZA, SUITE 4900
180 NORTH STETSON AVENUE
CHICAGO, IL 60601-6731

EXAMINER

EPPERSON, JON D

ART UNIT

PAPER NUMBER

1639

MAIL DATE

DELIVERY MODE

10/09/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/527,772	Applicant(s) TANAKA ET AL.	
	Examiner Jon D. Epperson	Art Unit 1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-11 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372. This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1.
2. In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.
 - I. Claims 1-7 drawn to a method of preparing a library of membrane proteins embedded in liposomes
 - II. Claims 8-11 drawn to a product described as a library of membrane protein-embedded liposomes
3. The inventions listed as Groups I-II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the reasons that follow.
4. PCT Rule 13.2 states that unity of invention shall be fulfilled when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features.” It further defines “special technical feature” as “those technical features that define a contribution which each of the claimed inventions, claimed as a whole, makes over the prior art.”

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5. The technical feature that links all of the claims is a library of membrane protein-embedded liposomes. The groups lack unity because this technical feature is known in the art as disclosed by Tanaka et al. (WO 02/056026 A1) (Date of Publication is **17 July 2002**). Tanaka et al. disclose a library of membrane protein-embedded liposomes (e.g., see Tanaka et al., page 8, especially lines 25-28, “membrane protein is embedded in an artificial liposome that models on the cell membrane lipid bilayer and membrane protein library is constructed”; see also page 9, especially lines 18-23, “isolating a membrane fraction from a cell sample and fusing the membrane fraction with liposomes to prepare a membrane protein library (a set of membrane protein-embedded liposomes) wherein all membrane proteins are attached to or penetrated into its lipid bilayer”).

6. Therefore, the technical feature linking the inventions of groups I-II does not constitute a species technical feature as defined by PCT Rule 13.2, as it does not define a contribution over the prior art. Group I is thus drawn to a method of preparing a library whereas Group II is drawn to a library. Accordingly, groups I and I are not so linked by the same or a corresponding special technical feature as to form a single general inventive concept.

Species Election

7. This application contains claims directed to more than one species of the generic invention for Groups I-II. These species are deemed to lack unity of invention because they are not so linked to form a single general inventive concept under PCT Rule 13.1.

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Group I

8. If applicant elects any one of the invention of Groups I or II applicant is required to elect from the following patentably distinct species. Claim 1 and 8 are generic for Groups I and II, respectively.

Subgroup 1: Species of compound of membrane protein (e.g., see claim 1)

Applicant must elect for purposes of search a *single species* of membrane protein such as G protein-coupled receptors, oligomer type receptors, etc. (e.g., see claim 2). Applicants must further elect a specific protein with these classes such as urokinase, C5a, interferon- γ receptor, etc. 9e.g., see specification, page 39, first full paragraph).

Subgroup 2: Species of liposome (e.g., see claim1)

Applicant must elect for purposes of search a *single species* of liposome such as that prepared from purified yolk lecithin (1.25 g) and cholesterol (.125g) (e.g., see specification, paragraph bridging pages 39 and 40).

9. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons.

10. PCT Rule 13.2 states that unity of invention shall be fulfilled when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features". It further defines "special technical feature" as "those technical features that define a contribution which each of the claimed inventions, claimed as a whole, makes over the prior art". For example, unity of invention is fulfilled if:

- (a) all alternatives have a common property; **and**
- (b) (i) a common structure is present, i. e. a significant structural element is shared by all alternatives, or

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(b) (ii) in cases where the common structure can not be the unifying criterion, all alternatives belong to a recognized class of compounds in the art to which the invention pertains. (MPEP 1850).

11. According to PCT Rule 13.2 and to the guidelines in Section (f)(i)(B)(1) of Annex B of the PCT Administrative Instructions, all alternatives of a Markush Group must have a common structure, which is a “significant” structural element. Although chemical compounds of formula (I) and/or (XIIC) share a common structure of, for example, a substituted heteroaromatic ring “A” and a double bond with Z, X and Y substituents, the compounds are not regarded as being of similar nature because the shared common structure is not a significant structural element. A “significant” structural element is not shared by all alternatives because formula (I) does not represent any known integrase-binding motif that will elicit the desired response. In fact, Yuan et al. (Yuan, H.; Parrill, A. L. “QSAR Studies of HIV-1 Integrase Inhibition” *Bioorganic & Medicinal Chemistry* 10 (2002) 4169-4183) disclose that no such binding motif exists ever for a more narrowly drawn class of HIV-1 integrase inhibitors because the art, according to Yuan et al., is unpredictable (e.g., see Yuan et al., abstract, “... a single unified understanding of the relationship between the structures and activities of these compound [i.e., integrase inhibitors] still eludes researchers”). Thus, the compounds represented by formula (I) and/or (XIIC) do not share a “significant” structural element that produce a common property such as integrase inhibition. Furthermore, the compounds represented by formulas (I) and (XIIC) do not all belong to an art-recognized class of compounds (e.g., the compounds can be separately classified depending on the nature of the ring substituent such as thiophene = class 544, subclass 146; imidazole = class 548, subclass 335.1, etc.). Likewise, the additional components of the composition for subgroup 2 do not share a common property and a common structure (e.g., see

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claim 21 wherein the reverse transcriptase inhibitors and the protease inhibitor would have different structures and functions). Finally, According to PCT Rule 13.2, unity of invention exists only when the shared same or corresponding technical feature is a contribution over the prior art. Thus, even if assuming arguendo that all of the claimed alternatives did have a “significant” common structure (which is not the case, see above) the compounds would not be regarded as being of similar nature because the shared common structure is not a contribution over the prior art. The “special technical feature” of Groups I-IV lack novelty or inventive step over Thomson et al. and, as a result, do not make a contribution over the prior art (see above).

For these reasons, election under these rules is proper and required.

12. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

13. Applicant is advised that a reply to this requirement **must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added.** An argument that a claim is allowable or that all claims are generic is considered **nonresponsive** unless accompanied by an election.

14. Upon the allowance of a generic claim, applicant will be entitled to consideration of

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claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, **applicant must indicate which are readable upon the elected species**. MPEP § 809.02(a).

15. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143). Because the above restriction/election requirement is complex, a telephone call to applicants to request an oral election was not made. See MPEP § 812.01.

16. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

17. Applicant is also reminded that a 1 - month (not less than 30 days) shortened statutory period will be set for response when a written requirement is made without an action on the merits. This period may be extended under the provisions of 37 CFR 1.136(a). Such action will not be an "action on the merits" for purposes of the second action final program, see MPEP 809.02(a).

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18. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained.

Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jon D Epperson whose telephone number is (571) 272-0808. The

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examiner can normally be reached Monday-Friday from 9:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James (Doug) Schultz can be reached on (571) 272-0763. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Jon D. Epperson/

Primary Examiner, AU 1639